PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Impact of LVAD Implantation on Micro- and Macrovascular Function

Trial Acronym

LVAD

URL of the trial

[---]*

Brief Summary in Lay Language

End stage heart failure is characterized by a critical inability of the heart to meet the organism's blood demand even under resting conditions. Heart transplantation (HTx) is the established therapeutic approach in the treatment of end stage heart failure and still the gold standard treatment. Left ventricular assist devices (LVADs) are considered as a vital therapeutic option to temporarily or permanently assist the failing circulation. The hemodynamic vascular consequences of implanting LVADs have not been studied in detail. The aim of the study is to investigate the effect of LVAD implantation compared to heart transplant (HTx) on micro- and macrovascular function in patients with end stage heart failure.

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00008376**
- Date of Registration in DRKS: **2016/03/11**
- Date of Registration in Partner Registry or other Primary Registry: **2014/06/24**
-

DRKS-ID: **DRKS00008376**
Date of Registration in DRKS: **2016/03/11**
Date of Registration in Partner Registry or other Primary Registry: **2014/06/24**

Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02174133 (ClinicalTrials.gov)**
- Sponsor-ID: **LVAD (Klinik für Kardiologie, Pneumologie und Angiologie)**

Health condition or Problem studied

- Free text: **End Stage Heart Failure**
- ICD10: **I50 - Heart failure**

Interventions/Observational Groups

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **[---]***
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **[---]***
- Assignment: **[---]***
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Macrovascular function measured by flow-mediated vasodilation (FMD); time frame: 3 months after implantation

Secondary Outcome

- Microvascular function assessed by non-invasive laser Doppler imaging; time frame: 3 months after implantation
- microparticles determined by Flow Cytometry; time frame: 3 months after implantation

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Division of Cardiology, Pulmonology and Vascular Medicine Duesseldorf,, Duesseldorf**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2014/01/31**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **[---]***
- National/International: **[---]***

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- patients after HTX

- patients after LVAD implantation

- patients with stable coronary heart disease and normal systolic left ventricular function

- **healthy volunteers**
- **written informed consent**

Exclusion criteria

- **acute inflammation**
- **cardiac arrhythmia**
- **renal failure**
- **malignant disease**

Addresses

■ **Primary Sponsor**

Klinik für Kardiologie, Pneumologie und Angiologie

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Division of Cardiology, Pulmonology and Vascular Medicine
Christian Heiss, MD

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Public Queries**

Division of Cardiology, Pulmonology and Vascular Medicine
Christian Heiss, MD

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/07/01**

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 1
- Last processed date by ClinicalTrials.gov: 2015/05/04

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*